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Proposed Registration Decision PRD2015-26

(9Z,12E)-9,12-Tetradecadien-1-yl acetate

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Overview

Proposed Registration Decision for (9Z,12E)-9,12-Tetradecadien-1-yl acetate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Bedoukian Indian Meal Moth Technical and Cidetrak IMM, containing the technical grade active ingredient (9Z,12E)-9,12-tetradecadien-1-yl acetate, for use as a mating disruptant for Indian meal moth (*Plodia interpunctella*), tobacco moth (*Ephestia elutella*), raisin moth (*Cadra figulilella*), almond moth (*Cadra cautella*), and Mediterranean flour moth (*Ephestia kuehniella*).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Bedoukian Indian Meal Moth Technical and Cidetrak IMM.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on (9Z,12E)-9,12-tetradecadien-1-yl acetate, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on (9Z,12E)-9,12-tetradecadien-1-yl acetate, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is (9Z,12E)-9,12-tetradecadien-1-yl acetate?

(9Z,12E)-9,12-tetradecadien-1-yl acetate is a major component of the sex pheromone of several moth species that infest stored food and feed. In nature, this sex pheromone is produced by female moths and attracts male moths for mating. It is the active ingredient in the end-use product Cidetrak IMM, which disrupts the mating between adult males and females of several moth species that are major pests of stored food and feed.

Health Considerations

Can Approved Uses of (9Z,12E)-9,12-tetradecadien-1-yl Acetate Affect Human Health?

(9Z,12E)-9,12-Tetradecadien-1-yl acetate is unlikely to affect human health when used according to label directions.

Bedoukian Indian Meal Moth Technical Pheromone is unlikely to affect human health when it is used according to label directions. Straight chain lepidopteran pheromones (SCLPs) are naturally occurring compounds that are produced by many lepidopteran insect species (i.e. moths and butterflies) to communicate chemically with other members of the same species.

Exposure to the SCLP, (9Z,12E)-9,12-tetradecadien-1-yl acetate, may occur when handling or applying Cidetrak IMM or by entering storage areas that were previously treated with Cidetrak IMM. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

While toxicological information was not provided by the applicant to support Bedoukian Indian Meal Moth Technical Pheromone or Cidetrak IMM, the toxicology of SCLPs has been well characterized. In general, SCLPs are non-toxic compounds that are readily metabolized by most living organisms. Toxicity studies on SCLPs have also indicated no toxicity to mammals. Exposure to people from the use of Cidetrak IMM is not expected to be of concern. However, the hazard signal words, "CAUTION – EYE and SKIN IRRITANT" are required on the labels.

Residues in Water and Food

Dietary risks on food and water are not of health concern.

Dietary risks from food and drinking water are not expected to be of concern for (9Z,12E)-9,12-tetradecadien-1-yl acetate. Cidetrak IMM is contained within a discrete dispenser that is affixed in storage and manufacturing areas. Cidetrak IMM will not be applied directly to food or feed crops. Also, the end-use product label has precautionary statements not to contaminate food, feed, and water with the end-use product; therefore, dietary exposure to the SCLP from the proposed use is anticipated to be negligible. In addition, (9Z,12E)-9,12-tetradecadien-1-yl acetate is unlikely to enter drinking water sources since it is volatile and enclosed in a plastic dispenser. The PMRA has determined that a maximum residue limit (MRL) does not need to be specified for (9Z,12E)-9,12-tetradecadien-1-yl acetate under the *Pest Control Products Act*.

Occupational Risks From Handling the End-Use Product Containing (9Z,12E)-9,12-Tetradecadien-1-yl Acetate

Occupational risks are not of concern when used according to label directions.

Workers can come in direct contact with the commercial end-use product containing (9Z,12E)-9,12-tetradecadien-1-yl acetate while affixing dispensers in storage and manufacturing facilities and to a lesser extent through the inhalation of the volatile active ingredient. The label has adequate precautionary measures including the requirement of personal protective equipment and precautionary and hygiene statements to minimize exposure. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for workers, risk to these individuals are not a concern.

Residential and Bystander Exposure and Risk

As the application of Cidetrak IMM involves only authorized personnel, bystander exposure is expected to be minimal and not of concern when the end-use product is used according to the label directions. Residential exposure is also likely to be minimal when the label directions are followed for Cidetrak IMM.

Value Considerations

What Is the Value of Cidetrak IMM?

Cidetrak IMM disrupts mating of moth species which are major pests in stored food and feed so that they produce fewer offspring. This reduces the need to use insecticides in a pest management program.

Cidetrak IMM is a dispenser that is hung in stored food and feed facilities and releases the pheromone (9Z, 12E)-9,12-tetradecadien-1-yl acetate. It interferes with the ability of Indian meal moth, Mediterranean flour moth, tobacco moth, raisin moth and almond moth to find mates, thus reduces the number of offspring which feed on stored food and feed. It is intended to be used with other pest management practices, such as cleaning, and reduces the number of insecticidal treatments required in a pest management program. Mating disruption is a new way to manage moth pests in stored food and feed.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Cidetrak IMM to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The toxicological profiles of the technical grade active ingredient and the commercial end-use product raise no hazards of concern. The labels include hazard signal words and precautionary statements to identify the hazards and minimize human health risks. The following statements are included on the principal display panels of both the technical product and the end-use product labels: "CAUTION– SKIN and EYE IRRITANT".

To avoid direct contact with Cidetrak IMM on the skin and eyes, workers involved in the application must wear long sleeved shirt and chemical resistant gloves. Eye protection is not required for workers since the proposed method of application is expected to yield negligible eye exposure.

A restricted-entry interval is not required for Cidetrak IMM.

Next Steps

Before making a final registration decision on (9Z,12E)-9,12-tetradecadien-1-yl acetate, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on (9Z,12E)-9,12-tetradecadien-1-yl acetate (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

(9*Z*,12*E*)-9,12-Tetradecadien-1-yl acetate

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	(9*Z*,12*E*)-9,12-Tetradecadien-1-yl acetate
Function	Pheromone
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	(9*Z*,12*E*)-tetradeca-9,12-dien-1-yl acetate
2. **Chemical Abstracts Service (CAS)**	9,12-tetradecadien-1-ol, acetate, (9*Z*,12*E*)-
CAS number	30507-70-1
Molecular formula	$C_{16}H_{28}O_2$
Molecular weight	252.4
Structural formula	
Purity of the active ingredient	94.0%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Bedoukian Indian Meal Moth Technical Pheromone

Property	Result
Colour and physical state	Colourless liquid
Odour	Very mild, oily odour
Melting range	-40.03°C
Boiling point or range	319.40°C
Density	0.89 g/mL
Vapour pressure at 25°C	92.4 mPa
Ultraviolet (UV)-visible spectrum	No significant absorbance expected at λ > 300 nm

Property	Result
Solubility in water	0.090598 mg/L
Solubility in organic solvents	Fully soluble in polar and non-polar solvents
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} = 6.3278
Dissociation constant (pK_a)	Not applicable, does not dissociate
Stability (temperature, metal)	Product is stable for 14 days at room temperature and at 54°C; product is stable for 14 days when exposed to iron, iron acetate, aluminum and aluminum acetate at room temperature and at 54°C. Note that a colour change occurred after 14 days when exposed to iron acetate at 54°C

End-Use Product—Cidetrak IMM

Property	Result
Colour	Black
Odour	Mild, waxy
Physical state	Solid polyvinyl pheromone-impregnated dispenser
Formulation type	SR (slow release generator)
Guarantee	3.29%
Container material and description	3 g PVC strip/dispenser (6.7 × 2.4 cm) impregnated with pheromone; 56 dispensers are packaged in a foil pouch
Density	Not applicable, product is a slow release generator
pH of 1% dispersion in water	Not applicable, product is a slow release generator
Oxidizing or reducing action	No oxidizing or reducing action
Storage stability	Study in progress, to be provided
Corrosion characteristics	Non-corrosive
Explodability	Not explosive

1.3 Directions for Use

Cidetrak IMM suppresses Indian meal moth, Mediterranean flour moth, tobacco moth, raisin moth and almond moth by mating disruption. Cidetrak IMM is applied at a rate of one dispenser per 100 to 300 m^3 in storage and manufacturing facilities containing raw grains, bean seeds, tobacco, birdseed, spices, nuts, dried commodities and animal feed. Dispensers are secured in a grid pattern at a height of 1.5 to 4.8 m within buildings at locations such as walls or pallets. (9*Z*,12*E*)-9,12-Tetradecadien-1-yl acetate is slowly released into the area from each dispenser for approximately 150 to 190 days.

1.4 Mode of Action

(*9Z,12E*)-9,12-tetradecadien-1-yl acetate is a pheromone that disrupts mating between adult males and females of several moth pests that infest stored food and feed. The end result is that males fail to find females for mating and therefore the females cannot lay fertile eggs so that the pest population is reduced or eliminated.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The method provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

While toxicology information or data were not submitted in support of Bedoukian Indian Meal Moth Functional Pheromone or Cidetrak IMM, SCLPs have been well characterized as having non-toxic modes of action with known low mammalian toxicity and no evidence of mutagenicity or other long term effects. With an established history of exposure to humans and the environment with no known adverse effects other than mating disruption within the targeted lepidopteran insect population, it is generally accepted that SCLP-containing products will pose minimal risk to human health. Therefore, reduced toxicological data requirements have been established by PR98.8 for SCLPs and all are judged to be toxicologically equivalent.

Available acute toxicity data on various SCLPs indicate low oral toxicity (LD_{50} >5000 mg/kg, practically nontoxic), low dermal toxicity (LD_{50} >2000 mg/kg, practically nontoxic), low inhalation toxicity (LC_{50} generally >5 mg/L, practically nontoxic), and no evidence of mutagenicity (Ames Salmonella assay). Although limited in number, available short-term toxicity studies also indicate SLCPs pose no long-term health concerns in mammals. A 90-day feeding study in the rat was conducted at doses up to 1 g/kg of a commercial blend of branched acetates with an aliphatic chain length between C 10 and C 14. The results indicated no significant signs of toxicity other than those expected from longer-term exposure to high doses of a hydrocarbon, namely, histopathologic evidence of nephropathy in males and increased liver and kidney weights in both sexes. A developmental toxicity study in the rat involving inhalation exposure to unbranched, primary alcohols with chain length C8 to C 10 indicated no detectable developmental toxicity.

SCLPs are readily metabolized by enzyme systems present in most living organisms and should therefore present no risk to individuals with normal physiology. SCLPs, like other long-chain fatty acid molecules, are metabolized either by β-oxidation or by forming complexes with glucuronide and excreted by the kidneys.

The formulated product, Ciderak IMM, is contained within a passive, slow-release, discrete dispenser. Therefore, the potential for direct human exposure to the active ingredient is considered low. The Materials Safety Data Sheet for the technical grade of active ingredient, however, noted that this product may be irritating to the skin and eyes. Consequently, the statement, "CAUSE EYE& SKIN and EYE IRRITATION", is required on the primary panel of both labels.

Based on all of the available data for SCLPs, there is no evidence of increased susceptibility of infants and children in comparison to adults that may result from exposure to SCLPs. Furthermore, there is no evidence that SCLPs have a potential to disrupt endocrine activity in humans.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website. Since (*9Z*,12E)-9,12-tetradecadien-1-yl acetate is a new active ingredient pending registration for use in Canada, there are no incident reports. Once products containing (*9Z*,12E)-9,12-tetradecadien-1-yl acetate are registered, the PMRA will monitor for incident reports.

5.2 Occupational and Bystander Exposure and Risk Assessment

5.2.1 Dermal Absorption

Due to the rapid volatility of (*9Z*,12E)-9,12-tetradecadien-1-yl acetate and the proposed use of Ciderak IMM (i.e., discrete dispenser), dermal absorption from the application of Ciderak IMM is expected to be minimal.

5.2.2 Use Description

Ciderak IMM consists of a plastic dispenser that is hung in and around storage and manufacturing areas that contain raw grains, bean seed, tobacco, birdseed, spices, nuts, dried commodities and animal feed. The active ingredient is slowly released from the dispenser resulting in a low concentration of pheromone in the atmosphere. A single dispenser, according to the use description, can treat between 100 and 300 m^3. Since there is a limited area where Ciderak IMM could be applied, applicators are expected to apply a maximum of 10 strips per day for a maximum of 8 weeks in Canada. Individual farmers or storage personnel would apply a maximum of 8 strips. Depending on temperature, the strips have an effective period of 120–150 days, therefore no more than 3 strips would be required per year per 100–300 m^3.

3.2.3 Mixer, Loader and Applicator Exposure and Risk

Occupational exposure to Cidetrak IMM is expected to be mainly by the dermal route and to a lesser extent the inhalation route during handling and placement of the dispensers in storage and manufacturing areas.

Mixing is not required, but the discrete dispensers require installation in storage and manufacturing areas. Since the end-use product is expected to be irritating to the skin and eyes, precautionary statements on the product label require the user to wear long sleeved shirt and chemical resistant gloves, and to not allow product to get in eyes or on skin and to wash hands with soap and water after use. Eye goggles are not required since negligible ocular exposure is expected from the method of application. Inhalation exposure is also not expected to be a concern due to the low acute inhalation toxicity of SCLPs to humans; a respirator is not required for use during handling or installation of the dispensers.

Clean-up activity is limited to the collection of depleted dispensers and no repair activities are anticipated.

3.2.4 Postapplication Exposure and Risk

Minimal postapplication exposure is expected when the end-use product is used according to label directions. Between applications, workers performing routine daily activities such as scouting for insects and disease, harvesting, pruning, and other maintenance practices should be able to avoid direct contact with the dispensers. Although no release rates were reported for (9Z,12E)-9,12-tetradecadien-1-yl acetate, the release rates are usually comparable or less than pheromone levels found naturally during pest outbreaks and, therefore, not of concern. A restricted-entry interval is not required for Cidetrak IMM.

3.2.5 Residential and Bystander Exposure and Risk

Due to the placement of the dispensers in storage and manufacturing areas, the volatility and rapid degradability of the components of Cidetrak IMM, and the rate of application of active ingredient being comparable to (or less than) natural background levels, bystander and residential exposure to (9Z,12E)-9,12-tetradecadien-1-yl acetate is expected to be negligible and not of concern.

3.3 Food Residue Exposure Assessment

3.3.1 Food and Drinking Water

Cidetrak IMM is formulated as a plastic strip that is affixed in storage and manufacturing sites containing raw grains and bean seeds. The active ingredient is slowly released from the dispenser, resulting in a low concentration of pheromone in the atmosphere. Therefore, the use of Cidetrak IMM formulated with Bedoukian Indian Meal Moth Technical Pheromone is not expected to result in unacceptable dietary risks when the product is used according to label directions. In addition, as the active ingredient is volatile and enclosed in a polymeric dispenser, exposure to the technical grade active ingredient in drinking water is not expected to occur.

3.3.2 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products, when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

Cidetrak IMM is formulated as a solid-matrix dispenser which is not in direct contact with a food crop. Given the low acute, short-term and chronic toxicity of SCLPs and the anticipated negligible levels of dietary exposure, the specification of an MRL is not required for (9Z,12E)-9,12-tetradecadien-1-yl acetate under the *Pest Control Products Act*.

4.0 Value

4.1 Consideration of Benefits

Although mating disruption has historically been used to control pests in both agriculture and forestry, Cidetrak IMM represents the first product for mating disruption of pests in stored food and feed. Moths in stored food and feed are usually controlled using commercial class insecticides, such as pyrethrins and silicon dioxide, or restricted class fumigants, such as phosphine. The novel approach of mating disruption of moths in stored food and feed is to be used in an integrated pest management (IPM) program that includes monitoring and sanitation. The use of Cidetrak IMM has shown to reduce the number of treatments with an insecticide in stored food and feed areas.

Another benefit of pheromone-based mating disruption is that development of resistance to the use of pheromones is considered to be unlikely. Also, when the use of mating disruption reduces the need for applications of conventional chemical insecticides, selection pressure for possible development of resistance to those insecticides may be reduced.

4.2 Effectiveness Against Pests

Six operational efficacy trials conducted in warehouses, manufacturing facilities and retail outlets in Australia and throughout the United States investigated the efficacy of Cidetrak IMM or a prototype formulation against Indian meal moth or a combination of Indian meal moth, Mediterranean flour moth, tobacco moth and almond moth. An additional laboratory study contributed to establishing the duration that Cidetrak IMM releases pheromone. (9Z,12E)-9,12-tetradecadien-1-yl acetate is the primary sex pheromone component of Indian meal moth, Mediterranean flour moth, tobacco moth, raisin moth and almond moth. Based on the submitted efficacy studies and extrapolation from Indian meal moth to other moth species, Cidetrak IMM applied at a rate of 1 dispenser per 100 to 300 m^3 suppresses Indian meal moth, Mediterranean flour moth, tobacco moth, raisin moth and almond moth in storage and manufacturing facilities containing various food and feed for 130 to 150 days depending on temperature. Many of these studies also reported a reduction in the number of conventional insecticide applications that were needed.

4.3 Non-Safety Adverse Effects

Because the product is contained within a dispenser from which it is released slowly into the air, non-safety adverse effects (for example, discolouration) are not expected.

4.4 Supported Uses

Value information supports the use of Cidetrak IMM for suppression of Indian meal moth, almond moth, Mediterranean flour moth, the tobacco moth and the raisin moth in stored food and feed by mating disruption. Cidetrak IMM is applied in a grid pattern at a rate of one dispenser per 100 to 300 m^3 in storage and manufacturing facilities containing raw grains, bean seeds, tobacco, birdseed, spices, nuts, dried commodities and animal feed. The pheromone, (9Z,12E)-9,12-tetradecadien-1-yl acetate, is slowly released into the area from the dispenser for approximately 130 to 150 days.

5.0 Pest Control Product Policy Considerations

5.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, Bedoukian Indian Meal Moth Technical Pheromone and Cidetrak IMM containing (9Z,12E)-9,12-tetradecadien-1-yl acetate were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Bedoukian Indian Meal Moth Technical Pheromone does not meet Track 1 criteria as the active ingredient is not highly toxic, and is not expected to be persistent in the environment or to bioaccumulate.

- There are also no formulants, contaminants or impurities present in the end-use product that would meet the TSMP Track 1 criteria.

5.2 Formulants and Contaminants of Health Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Bedoukian Indian Meal Moth Technical Pheromone and Cidetrak IMM do not contain any other formulants or contaminants of environmental concern identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641-2643:List of Pest Control Product Formulants of Health or Environmental Concern

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and DIR2006–02.

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-11-30) pages 2641-2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613: *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New Pest Control Products Act

8 Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

6.0 Summary

6.1 Human Health and Safety

The technical product, Bedoukian Indian Meal Moth Technical Pheromone, and end-use product, Cidetrak IMM, are expected to be of low acute toxicity via the oral, dermal, and inhalation routes. They are not considered to be dermal sensitizers, but they are considered to be mildly irritating to the skin and eyes. Bedoukian Indian Meal Moth Technical Pheromone and Cidetrak IMM are also considered to be non-mutagenic.

Worker, bystander and residential exposures to (9Z,12E)-9,12-tetradecadien-1-yl acetate as a result of the proposed use patterns are not expected to result in unacceptable risk when Cidetrak IMM is used according to label directions.

Dietary exposure to (9Z,12E)-9,12-tetradecadien-1-yl acetate from the use of Cidetrak IMM is not expected to result in unacceptable dietary risks when the product is used according to label instructions. The specification of an MRL is not required for (9Z,12E)-9,12-tetradecadien-1-yl acetate under the *Pest Control Products Act*.

6.2 Value

Cidetrak IMM suppresses Indian meal moth, almond moth, Mediterranean flour moth, the tobacco moth and the raisin moth in manufacturing facilities containing stored food and feed. It is to be used in a pest management program that includes monitoring and sanitation and reduces the need for conventional insecticides to control these major moth pests. It is unlikely that moths would develop resistance to this product and it may help to reduce selection pressure for resistance for to conventional pest control products.

7.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Bedoukian Indian Meal Moth Technical Pheromone and Cidetrak IMM, containing the technical grade active ingredient (9Z,12E)-9,12-tetradecadien-1-yl acetate, to supress moths in stored food and feed.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

CAS	Chemical Abstracts Service
cm	centimetres
DACO	data code
g	gram
ha	hectare(s)
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
m	metre(s)
mg	milligram
mL	millilitre
MRL	maximum residue limit
MS	mass spectrometry
PCPA	*Pest Control Product Act*
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PVC	polyvinyl chloride
SCLP	straight chain lepidopteran pheromone
SR	slow release
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UV	ultraviolet

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	References
2357961	Bedoukian Indian Meal Moth Technical Pheromone - manufacturing summary, DACO: 2.11.1 CBI
2357962	Bedoukian Indian Meal Moth Technical Pheromone - starting materials, DACO: 2.11.2 CBI
2357963	Bedoukian Indian Meal Moth Technical Pheromone - process, DACO: 2.11.3 CBI
2357967	Bedoukian Indian Meal Moth Technical Pheromone - impurities, DACO: 2.11.4 CBI
2357968	Bedoukian Indian Meal Moth Technical Pheromone - limits, DACO: 2.12.1 CBI
2357969	Bedoukian Indian Meal Moth Technical Pheromone - GC/MS, DACO: 2.13.2 CBI
2357971	Bedoukian Indian Meal Moth Technical Pheromone - properties, DACO: 2.14 CBI
2357972	Bedoukian Indian Meal Moth Technical Pheromone - batch data, DACO: 2.13.3 CBI
2357974	Bedoukian Indian Meal Moth Technical Pheromone method val, DACO: 2.13.1 CBI
2357975	Bedoukian Indian Meal Moth Technical Pheromone - stab study, DACO: 2.14.13 CBI
2464610	2014, Detailed Manufacturing Process Description for Bedoukian Indian Meal Moth Technical Pheromone Sub # 2013-5948, DACO: 2.11.3 CBI
2464611	2014, Batch data for Bedoukian Indian Meal Moth Technical Pheromone Sub # 2013-5948, DACO: 2.13.3 CBI
2468135	2014, Batch Data for High Purity Bedoukian Indian Meal Moth Pheromone Sub 2013-5948, DACO: 2.13.3 CBI
2492337	2015, Spectral confirmation of impurities for submission # 2013-5948, DACO: 2.13.2 CBI
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2356639	2007, Product identity and Composition of Cidetrak IMM, DACO: 3.2.1,3.2.2,3.2.3 CBI
2356641	2013, Analytical Procedure for Extraction and Analysis of Cidetrak IMM MD Polyvinylchloride Polymer Dispensers, DACO: 3.4.1 CBI
2521423	2007, Product Identity and Composition of Cidetrak IMM (amended), DACO: 3.2.2 CBI
2521424	2015, Chemistry-3.2-Cidetrak-EP, DACO: 3.2.1,3.2.2
2521425	2015, Enforcement Analytical Method of Cidetrak IMM -Validation of Analytical Methodology for the Assay of Active Ingredient, DACO: 3.4.1 CBI
2521426	2015, Chemistry-3.5.10-20150410121211855, DACO: 3.5.10

2.0 Human and Animal Health

PMRA Document Number	References
2356611	2013, Exposure-5.2-Cidetrak-Use Description Scenario, DACO: 5.2

3.0 Value

PMRA Document Number	References
2356617	2013, Summary of Storage Insect Control with Cidetrak-IMM, DACO: 10.1, 10.2.3.1
2356619	2009, CIDETRAK IMM an Effective Mating Disruption Product for the Control of Indian meal Moths, *Plodia interpunctella*, in Peanut Storages, DACO: 10.2.3.3(C)
2356621	1998, Report on Cidetrak IMM Performance in Earliest Trials in Northeast Victoria Australia, DACO: 10.2.3.3(C)
2356623	2009, CIDETRAK IMM Mating Disruption Compared to Conventional Insecticides for Management of Indian Meal Moth, *Plodia interpunctella*, in a Cocoa Bean Warehouse, DACO: 10.2.3.3(C)
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2521420	2010, Advances in Indian meal Moth Pest Management for Retail: Nationwide Program Overview, DACO: 10.2.3.4
2521421	2010, Evaluation of Monitoring Data from the Retail Pet Store Mating Disruption Project Part 1 (Summary), DACO: 10.2.3.4
2521422	2014, Release Rate Study of CIDETRAK IMM Polyvinylchloride Polymer (PVC) Dispensers, DACO: 10.6 CBI
2538043	2010, CIDETRAK IMM Mating Disruption Application for Management of Indian Meal Moth, *Plodia interpunctella*, in Animal Feed Retail Center and Related Feed Storage Warehouses Claremore, OK, DACO: 10.2.3.4
2538044	2010, INDIANMEAL MOTH MD *Plodia interpunctella* CIDETRAK IMM EXPERIMENT AND RESULTS , DACO: 10.2.3.4
2538045	2010, Advances in Indian meal Moth Pest Management for Retail: Nationwide Program Overview, DACO: 10.2.3.4
2538046	2014, Evaluation of Monitoring Data from the Retail Pet Store Mating Disruption Project Part 2 (Summary), DACO: 10.2.3.4

B. Additional Information Considered

Published Information

1.0 Value

PMRA Document Number	References
2540546	Burks and Kuenen, 2012. Effect of mating disruption and lure load on the number of *Plodia interpunctella* (Hübner) (Lepidoptera: Pyralidae) males captured in pheromone traps. Journal of Stored Products Research, 49: 189-195. 10.2.1